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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,735	10/18/2004	BANDI PARTHASARADHI REDDY	H1089/20022	2558
3000 7590 08/25/2008 CAESAR, RIVISE, BERNSTEIN, COHEN & POKOTILOW, LTD. 11TH FLOOR, SEVEN PENN CENTER 1635 MARKET STREET PHILADELPHIA, PA 19103-2212			EXAMINER CHANG, CELIA C	
			ART UNIT 1625	PAPER NUMBER
			NOTIFICATION DATE 08/25/2008	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@crbcp.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/511,735	<b>Applicant(s)</b> PARTHASARADHI REDDY ET AL.	
	<b>Examiner</b> Celia Chang	<b>Art Unit</b> 1625	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 May 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11, 14-24, 26 and 27 is/are pending in the application.
- 4a) Of the above claim(s) 1-11, 20-24, 26 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/7/08</u> .  | 6) <input type="checkbox"/> Other: _____                          |

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**DETAILED ACTION**

1. The response filed by applicants dated May 7, 2008 have been entered and considered carefully.

Claims 12-13, 15 have been canceled. Claims 14-19 are pending. Claims 1-11, 20-24, 26-27 stayed withdrawn from consideration.

2. The rejection of claims 14-19 under 35 USC 103(a) over WO 97/46527 is maintained for reason of record.

The gist of applicants argument is that there is no suggestion by the prior art to select solvents, thus, lacking suggestion or motivation to one skilled in the art to pick and choose alternative solvents.

Contrary to applicants' description, the parallel process between the prior art and the instant claim is:

Prior art (example 31):

Donepezil+methanol+H<sub>2</sub>O+HCl == Donepezil HCl, +di-isopropylether,



get a product which is Donepezil HClcrystal+5.5% water

Instant (example 4):

Donepezil+CCl<sub>3</sub>+H<sub>2</sub>O+HCl == DonepezilHCl, +di-isopropylether



get a product which is Donepezil HClcrystal+monohydrate (about 5% water)

Please note that the prior art process and the instant process made:

a) the same hydrated product;

b) the prior art product and the instant claims have substantial similar powdered x-ray diffraction patterns:

i)compare figure 1 of '527 and instant fig.3, see the similarity in triplets, splits etc.

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ii) compare peaks of '527 for polymorph I on pages 4-5 and peaks of claim 14. Seven out of the ten peaks in claim 14 are within the  $\pm 0.2\theta$  of each other and they are:

<u>'527</u>	<u>instant claim 14</u>
12.66	12.7
13.12	13.2
16.08	16.2
19.94	20.0
21.22	21.3
22.98	23.1
23.92	23.9

c) the steps are substantially similar except for the dissolving solvent which is methanol in prior art and chloroform in the instant claims.

d) in examples 30-44 of the '527 reference, a varieties of solvent were used to produce the same identical form containing about 5% water. The solvents are methanol, ethanol, tetrahydrofuran, acetonitrile; and the antisolvent to induce crystallization can optionally be used which are isopropylether, t-butylmethyl ether.

Therefore, contrary to attorney's misinterpretation, the reference not only provided factual evidence that the *same identical product* was made but also suggested that variation of solvents would be an optional elements to one having ordinary skill. Although changing solvents may result in different crystalline form, in so far as crystalline donepezil hydrochloride monohydrate is concerned, variation of solvent *is* prima facie because the *same crystalline product* is made and the solvent variation is within the obviousness in operation to maintain crystalline order supported by the reference.

3. The rejection of claims 14-19 under 35 USC 112 first paragraph and the rejection under 35 USC 102(g) are maintained for reason of record.

Please note that the 112 rejection is correlated to the above factual evidence that in so far as the donepezil hydrochloride monohydrate is concerned, changing solvent/mixture solvent is prima facie **in absence** of unexpected results. If the employing of di-isopropyl ether and t-butylmethyl ether can be shown by factual evidence to produce "different" products, then the claims lack enabling support from the specification that "all solvent/mixture solvent" is operable and the 112 first paragraph rejection is proper.

If the employing of di-isopropyl ether and t-butylmethylether can be shown by factual evidence to produce the "same" product, then, the 102(g) issued must be considered since the

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application dates are sufficiently close as to required factual support in consideration of an interference proceeding.

**4. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**5.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*OACS/Chang*  
*Aug. 15, 2008*

*/Celia Chang/*  
*Primary Examiner*  
*Art Unit 1625*